

Message Text

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61

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TO AMCONSUL HONG KONG

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EO 11652: N/A

TAGS: BBAK, HK

SUBJECT:REGULATIONS ON PRODUCTION AND SALE OF "SOFT" CONTACT LENSES

REF: HONG KONG 4623

1. SOFT CONTACT LENSES ARE REGARDED AS A "NEW DRUG" AS DEFINED IN THE FEDERAL FOOD DRUG AND COSMETIC ACT. AS SUCH, EACH NEW SOFT CONTACT LENS MUST BE EVALUATED AND APPROVED BY FDA UNDER THE USUAL PROCEDURES FOR ALL NEW DRUGS. A COPY OF THE NEW DRUG REGULATIONS AND THE CLINIC GUIDELINES FOR CONTACT LENSES ARE BEING FORWARDED BY POUCH.

2. CURRENTLY APPROVED SOFT CONTACT LENSES ARE:

A. "SOFLENS" CORRECTIVE LENS, MANUFACTURED BY BAUSCH AND LOMB, ROCHESTER, N.Y.

B. "HYDROCURVE" (HEFILCON A) CONTACT LENTS (CORRECTIVE) MANUFACTURED BY SOFT LENSES INC., SAN DIEGO, CALIFORNIA.

C. "SOFTCON" BANDAGE LENS, MANUFACTURED BY WARNER-LAMBERT, MORRIS PLANIS, N.J. SOFTCON IS APPROVED FOR BULLOUS KERATOPATHY AND DOES NOT PROVIDE VISUAL CORRECTION.

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